SEP 1 9 2001

510(k) Summary

K012393

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3831

Contact Person: Sherri L. Coenen

Date Prepared: July 25, 2001

Device Name

Proprietary name: Tina-quant Transferrin ver.2

Common name: Transferrin

Classification name: Transferrin immunological test system

Device Description

The Tina-quant Transferrin ver.2 Assay is based on the principle of immunological agglutination. Human transferrin forms a precipitate with a specific antiserum which is determined turbidimetrically at 340 nm.

Intended use

The cassette COBAS Integra Tina-quant Transferrin ver.2 contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative immunological determination of human transferrin in serum.

Indications for Use

A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum and plasma. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

Substantial Equivalence

The Tina-quant Transferrin ver.2 is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the COBAS Integra Tina-quant Transferrin (K951595).

Substantial equivalence - similarities

The following table compares the Tina-quant Transferrin ver.2 Assay with the predicate device.

Feature	Tina-quant Transferrin ver.2	Transferrin
Intended Use	The cassette COBAS Integra Tina-quant Trasferrin ver.2 (TRSF2) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative immunological determination of human transferrin in serum.	The cassette COBAS Integra Transferrin (TRSF) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative immunological determination of human transferrin in serum.
Indication for Use	A transferrin immunological test system is a device that consists of the reagents used to measure by immunological techniques the transferrin (an iron-binding and transporting serum protein) in serum and plasma. Measurement of transferrin levels aids in the diagnosis of malnutrition,acute inflammation, infection, and red blood cell disorders,such as iron deficiency anemia.	A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and other body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

Substantial equivalence - similarities

The following table compares the Tina-quant Transferrin ver.2 Assay with the predicate device.

Feature	Tina-quant Transferrin ver.2	Transferrin
Assay Protocol	Immunoturbidimetric assay	Immunoturbidimetric assay
Instrument	COBAS Integra Clinical Chemistry Analyzers	COBAS Integra Clinical Chemistry Analyzers
Traceability / Standardization	Standardized against the reference preparation CRM 470, corresponding to RPPHS (Reference Preparation Protein in Human Serum)	Standardized against the reference preparation CRM 470, corresponding to RPPHS (Reference Preparation Protein in Human Serum)

Substantial equivalence - differences

The following table compares the Tina-quant Transferrin ver.2 Assay with the predicate device.

Feature	Tina-quant Transferrin ver.2	Transferrin
Sample Type	Human serum and plasma	Human serum
Measuring Range	1.3 – 520 mg/dL	80 – 1280 mg/dL

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Tina-quant Transferrin ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Transferrin ver.2	Transferrin
Intra-assay precision (% CV)	0.86% at 1.35 g/L 0.77% at 3.36 g/L	1.5% at 1.10 g/L 0.83% at 3.32 g/L
Between Day Precision (% CV)	1.8% at 1.32 g/L 1.9% at 3.70 g/L	1.6% at 1.10 g/L 0.97% at 3.32 g/L
Limitations	• Icterus: No significant interference • Hemolysis: No significant interference • Lipemia: No significant interference up to an Intralipid level of 500 mg/dL • Rheumatoid factors: No significant interference • Interference of Gammopathy type IgM (Waldenstroem) sera is recognized by the "High Activity" check. In case samples are flagged "High Act", correct results can be obtained after post-dilution.	• Icterus: No significant interference • Hemolysis: No significant • Lipemia: No significant interference • Rheumatoid factors: No significant interference
Analytical sensitivity (LDL)	0.013 g/L	0.58 g/L
Method comparison	Tina-quant Transferrin ver.2 (Y) / COBAS Integra Transferrin (X) y = 1.06x + 0.03 r = 0.996	Transferrin (Y)/ nephelometric determination (X) y = 1.06x + 0.01 g/L r = 0.958

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Tina-quant Transferrin ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Transferrin ver.2	Transferrin
Calibration frequency	• after reagent lot change	• after reagent lot change
Expected values	2.0 – 3.6 g/l (200 – 360 mg/dl)	2.0 – 3.6 g/l (200 – 360 mg/dl)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 9 2001

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K012393
Trade Name: Roche Diagnostics Tina-quant® Transferrin ver.2
Regulatory Class: 21 CFR § 866.5880
Regulatory Class: II
Product Code: DDG
Dated: July 25, 2001
Received: July 27, 2001

Dear Ms. Coenen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Roche Diagnostics Corp.

510(k) Number (if known): K012393

Device Name: Tina-quant Transferrin ver.2

Indications For Use:

The cassette COBAS Integra Tina-quant Transferrin ver.2 contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative immunological determination of human transferrin in serum and plasma. A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum and plasma. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan S Altaire

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012393